COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 03-VI-2005
C(2005)1734

NOT FOR PUBLICATION

COMMISSION DECISION

of 03-VI-2005

amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160

ONLY THE GERMAN TEXT IS AUTHENTIC

COMMISSION DECISION

of 03-VI-2005

amending the marketing authorisation for "Ariclaim - duloxetine hydrochloride", a medicinal product for human use, granted by Decision C(2004)3160

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the third subparagraph of Article 4(5) thereof,

Having regard to the notifications submitted by Boehringer Ingelheim International GmbH under Article 4(1) of Regulation (EC) No 1085/2003,

Whereas:

(1) The European Medicines Agency acknowledged, between 8 September 2004 and 8 March 2005, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.

(2) The marketing authorisation should be updated, and Decision C(2004)3160 of 11 August 2004 amended accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3160 should therefore be replaced,

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[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

[2] OJ L 159, 27.6.2003, p. 24.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3160 is amended as follows:

1) The list of notifications for minor variations of type IA, the validity of which was acknowledged between 8 September 2004 and 8 March 2005, is added to the updated marketing authorisation;

Application number	Scope (EU numbers affected)
EMEA/H/C/552/IA/001	8.b.1 (IA) (EU/1/04/283/001-006)

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III B is replaced by the text set out in Annex III B to this Decision.

Article 2

This Decision is addressed to Boehringer Ingelheim International GmbH, Binger Strasse 173, D-55216 Ingelheim am Rhein, Deutschland.

Done at Brussels, 03-VI-2005

For the Commission
Günter VERHEUGEN
Member of the Commission